NOTICES OF SUPPLEMENTAL PROPOSED RULEMAKING

After an agency has filed a Notice of Proposed Rulemaking with the Secretary of State's Office for *Register* publication and the agency decides to make substantial changes to the rule after it is proposed, the agency must prepare a Notice of Supplemental Proposed Rulemaking for submission to the Office, and the Secretary of State shall publish the Notice under the Administrative Procedure Act (A.R.S. § 41-1001 et seq.). Publication of the Notice of Supplemental Proposed Rulemaking shall appear in the *Register* before holding any oral proceedings (A.R.S. § 41-1022).

NOTICE OF SUPPLEMENTAL PROPOSED RULEMAKING

TITLE 4. PROFESSIONS AND OCCUPATIONS

CHAPTER 18. NATUROPATHIC PHYSICIANS MEDICAL BOARD

Editor's Note: The following Notice of Proposed Rulemaking was exempt from Executive Order 2012-03 as issued by Governor Brewer. (See the text of the executive order on page 3268.)

[R12-237]

PREAMBLE

1. Citations to the agency's Notice of Rulemaking Docket Opening, the Notice of Proposed Rulemaking, and any other Notices of Supplemental Proposed Rulemaking (if applicable) as published in the *Register* as specified in R1-1-409 (A). A list of any other related notices published in the *Register* to include

Notice of Rulemaking Docket Opening: 18 A.A.R. 1869, August 3, 2012

Notice of Proposed Rulemaking: 18 A.A.R. 1821, August 3, 2012

2. Article, Part, or Section Affected (as applicable) — **Rulemaking Action**

R4-18-101	Amend
R4-18-801	Amend
R4-18-802	Amend
Article 9	New Article
R4-18-901	New Section
R4-18-902	New Section
R4-18-903	New Section
R4-18-904	New Section

3. Citations to the agency's statutory rulemaking authority to include both the authorizing statute (general) and the implementing statutes (specific):

Authorizing statute: A.R.S. § 32-1504(A)(1)

Implementing statutes: A.R.S. §§ 32-1501(15), 32-1501(31)(y), 32-1501(31)(z), 32-1501(31)(dd), 32-1501(31)(xx), 32-1504(A)(7), 32-1504(A)(8), 32-1526, 32-1527, 32-1530, 32-1581

4. The agency's contact person who can answer questions about the rulemaking:

Name: Gail Anthony, Deputy Director
Address: 1400 W. Washington, Suite 300
Phoenix, AZ 85007
Telephone: (602) 542-8242
Fax: (602) 542- 8804
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Name: Kathleen Phillips, Deputy Director
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Phoenix, AZ 85007
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5. An agency's justification and reason why a rule should be made, amended, repealed, or renumbered, to include an explanation about the rulemaking:

The Board is amending its definitions in R4-18-101 for clarification purposes and to eliminate the definitions that are already provided in statute.

The Board is amending R4-18-801 by including the requirements found in the definition of informed consent rather than keep the requirements in the definition in R4-18-101 and adding a provision that specifies when the Board considers a procedure, medication, or device experimental.

A.R.S. § 32-1581(A) requires a naturopathic physician to obtain Board certification before dispensing a natural substance, drug, or device. A.R.S. § 32-1504(A)(7) requires the Board to adopt rules relating to the dispensing of natural substances, drugs, and devices. A drug is defined in A.R.S. § 32-1501(15) to include the intravenous administration of minerals and nutrients. A.R.S. § 32-1581(G) requires the Board to adopt rules for the safe administration of minerals, including Board certification before a physician prescribes or dispenses. A.R.S. § 32-1504(A)(8) requires the Board to adopt rules for the safe administration of intravenous nutrients and to identify and exclude substances that do not meet the criteria of nutrients suitable for intravenous administration. Because of these statutes, the Board is making a new Article 9 that contains rules for dispensing natural substances, drugs, and devices. These rules include the requirements for qualifications, application for a dispensing certificate, renewal of a certificate, and standards for dispensing. The Board is submitting this rulemaking to the Secretary of State's office in accordance with the exemption authorization under item 4 of Executive Order 2011-05, State Regulatory Rulemaking Moratorium.

6. A reference to any study relevant to the rules that the agency reviewed and either relied on or did not rely on in its evaluation of or justification for the rules, where the public may obtain or review each study, all data underlying each study, and any analysis of each study and other supporting material:

The Board did not review or rely on any study.

7. An explanation of the substantial change which resulted in the supplemental notice:

The following revisions were initiated by the Board:

In R4-18-101(6) the Board added a definition of "device" for consistency and application to all of Chapter 18.

In R4-18-101, the Board repealed the definition of "supervisor" for clarification purposes because there already is a definition of "direct supervision" and "general supervision" in the Board's organic statutes.

In R4-18-101(13), the Board added a definition of "medication" for consistency throughout all of Chapter 18.

In R4-18-101(15), the Board added a definition of "procedure," for consistency throughout all of Chapter 18.

In R4-18-101(16), the Board added a definition of "protocol" for consistency throughout all of Chapter 18.

In R4-18-801(2), the Board changed "or" to "and" as a term of inclusion rather than exclusion to make all of the provisions in the rule apply.

In R4-18-901(2), the Board added a definition of "auscultation" because the term is included in the definition of physical examination.

In R4-18-901(9), the Board amended the definition of "physical examination" for clarification purposes.

8. A showing of good cause why the rulemaking is necessary to promote a statewide interest if the rules will diminish a previous grant of authority of a political subdivision of this state:

Not applicable

9. The preliminary summary of the economic, small business, and consumer impact:

When used in the economic impact statement summary, annual cost/revenue are designated as minimal when less than $5,000, moderate when between $5,000 and $10,000, and substantial when greater than $10,000.

The Board will incur minimal expense to write the rules and enforce their requirements.

The elimination of the definitions in R4-18-101 should not result in any costs to a naturopathic physician, medical student, or medical assistant because they are already in A.R.S. § 32-1501. The same is true for adding clarifying definitions and moving the informed consent requirements to R4-18-801.

A naturopathic physician should not incur costs as a result of the clarifying changes in R4-18-801, which state when the Board considers a procedure, medication, or device experimental.

The requirements in R4-18-902 and R4-18-903 should not increase costs to applicants or naturopathic physicians because they are statutorily required to be certified to dispense natural substances, drugs, or devices. As a result, the rules are being made to codify the Board's current requirements for approvals to dispense. The costs for an application and the application fee are minimal. Most individuals meet the qualification requirements in R4-18-902 when they apply. However, the Board receives approximately two or three applications annually from individuals who do not meet the requirements in R4-18-902 and therefore must take a course. The course may be provided by any of the organizations in R4-18- 902 and also may be available on-line. The costs for obtaining the course should be minimal, with the on-line course being offered free of charge. The application costs as stated in R4-18-903 should also be min-

imal to an applicant or naturopathic physician. In order to determine whether it is safe to prescribe or dispense a natural substance, drug, or device, it is standard practice for naturopathic physicians to perform physical examinations and laboratory tests as necessary. These requirements should not increase costs to naturopathic physicians.

Naturopathic physicians often form business groups of up to three persons. These businesses should not realize any increase in costs from the rules.

Consumers should not be expected to pay more for the physical examinations and laboratory tests conducted by the physicians for health and safety reasons.

10. The agency's contact person who can answer questions about the economic, small business and consumer impact:

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Fax:	(602) 542- 8804
E-mail:	kathleen.philips@massageboard.az.gov

11. The time, place, and nature of the proceedings to make, amend, renumber or repeal the rule or, if no proceeding is scheduled, where, when, and how persons may request an oral proceeding on the supplemental proposed rule:

Oral and written comments will be accepted for 30 days after publication in the *Register* at the location listed in item 4 between 8:00 a.m. and 5:00 p.m., Monday through Friday, except state holidays.

An oral proceeding will be scheduled if requested in writing and sent to the attention of either of the persons in item 4. The close of record is 5:00 p.m., January 14, 2013, if no oral proceeding is requested. If an oral proceeding is requested, the close of record is 5:00 p.m. on the date of the oral proceeding.

12. All agencies shall list other matters prescribed by statute applicable to the specific agency or to any specific rule or class of rules. Additionally, an agency subject to Council review under A.R.S. §§ 41-1052 and 41-1055 shall respond to the following questions:

a. Whether the rule requires a permit, whether a general permit is used and if not, the reasons why a general permit is not used:

The Board issues a license, which falls within the definition of general permit.

b. Whether a federal law is applicable to the subject of the rule, whether the rule is more stringent than federal law and if so, citation to the statutory authority to exceed the requirements of federal law:

Federal law is not applicable to the subject of the rule.

c. Whether a person submitted an analysis to the agency that compares the rule's impact of the competitiveness of business in this state to the impact on business in other states:

The Board did not receive such an analysis from any person.

13. A list of any incorporated by reference material as specified in A.R.S. § 41-1028 and its location in the rules:

There are no incorporation by reference documents.

14. The full text of the rules follows:

TITLE 4. PROFESSIONS AND OCCUPATIONS

CHAPTER 18. NATUROPATHIC PHYSICIANS MEDICAL BOARD

ARTICLE 1. GENERAL PROVISIONS

Section
R4-18-101. Definitions

ARTICLE 8. EXPERIMENTAL MEDICINE

Section
R4-18-801. Experimental Medicine
R4-18-802. Informed Consent and Duty to Follow Protocols

ARTICLE 9. CERTIFICATE TO DISPENSE

Section
R4-18-901. Definitions
R4-18-902. Qualifications for a Certificate to Dispense
R4-18-903. Application for a Certificate to Dispense; Renewal
R4-18-904. Dispensing; Intravenous Nutrients

ARTICLE 1. GENERAL PROVISIONS

R4-18-101. Definitions

In addition to the definitions in A.R.S. §§ 32-1501 through 32-1581, the following definitions apply to this Chapter unless otherwise specified:

1. "Administrative completeness review" means the Board's process for determining that an applicant has provided, or caused to be provided, all of the application packet information and documentation required by statute or rule for an application for a license or certificate.
2. "Applicant" means a person requesting from the Board an initial, temporary, or renewal license or certificate.

~~"Application" or "application packet" means the forms, documents, and information the Board requires to be submitted by an applicant or on behalf of an applicant.~~

3. "Approved Specialty College or Program" means any postdoctoral training program that awards a medical specialist certificate and is approved by one of the following;
   a. The Council on Naturopathic Medical Education,
   b. The American Association of Naturopathic Physicians, or
   c. The Arizona Naturopathic Medical Association.
4. "Chief medical officer" means a physician who is responsible for a clinical, preceptorship, internship, or postdoctoral training program's compliance with state and federal laws, rules, and regulations.

~~"Clinical training program" means a clinical training program operated in conjunction with an approved school of naturopathic medicine.~~

5. "Continuing medical education" means courses, seminars, lectures, programs, conferences, and workshops related to subjects listed in A.R.S. § 32-1525(B), that are offered or sanctioned by one of the organizations referenced in R4-18-205(B).
6. "Device means the same as in A.R.S. § 32-1581(H)(1).
7. "Endorsement" means the procedure for granting a license in this state to an applicant who is currently licensed to practice naturopathic medicine by another state, district, or territory of the United States or by a foreign country that requires a written examination substantially equivalent to the written examination provided for in A.R.S. § 32-1525.
8. "Facility" means a health care institution as defined in A.R.S. § 36-401, office or clinic maintained by a health care institution or by an individual licensed under A.R.S. Title 32, Chapter 13, 14, 17, or 29, office or public health clinic maintained by a state or county, office or clinic operated by a qualifying community health center under A.R.S. § 36-2907.06, or an office or clinic operated by a corporation, association, partnership, or company authorized to do business in Arizona under A.R.S. Title 10.
9. "Informed consent" means a document, signed by a patient or the patient's legal guardian, ~~that verifies that the patient or legal guardian understands the type of treatment the patient is to receive, and whether the clinician is a physician, preceptee, or an intern who is treating the patient. If an experimental or investigational protocol is to be followed, the informed consent form shall clearly state that the patient understands the procedures to be carried out, the risks and benefits of the procedure, medication or device to be used, that the patient can withdraw at any time, that the patient is voluntarily complying, and that the protocol meets the requirements of the institutional review board that approves the protocol.~~ which contains the information in R4-18-802(A)(1), (A)(2), and (A)(3).
10. "Institutional review board" means a group of persons that reviews investigational or experimental protocols and approves ~~its~~ their use on animals or humans within an institution for the purposes of protecting the subjects of the investigational or experimental protocol from undue harm and assures that the research and its review is carried out according to guidelines of the United States Department of Health and Human Services, Office for Human Research Protection.
11. "Internship" means clinical and didactic training by a doctor of naturopathic medicine certified by the Board, in an institution, certified by the Board.
12. "License" means a document issued by the Board that ~~entitles~~ authorizes the individual to whom it is issued to practice naturopathic medicine.
13. "Medication" means the same as drug defined in A.R.S. § 32-1501(15) or natural substance defined in A.R.S. § 32-

1501(23).

14. "National board" means any of the following:
    a. The Federation of State Medical Licensing Boards,
    b. The National Board of Chiropractic Examiners,
    c. The National Board of Medical Examiners,
    d. The National Board of Osteopathic Examiners, or
    e. The North American Board of Naturopathic Examiners.

~~"Preceptorship" means clinical training of not more than 24 months duration, by a person who holds a degree of doctor of naturopathic medicine, and is certified by the Board for preceptorship training.~~

15. "Procedure" means an activity directed at or performed on an individual for improving health, treating disease or injury, or making a diagnosis.
16. "Protocol means an explicit detailed plan of an experimental medical procedure or test that is approved by an institutional review board.
17. "Resident physician in training" means a person who holds a degree of doctor of naturopathic medicine and is certified by the Board to diagnose and treat patients under supervision in an internship, preceptorship, or a post doctoral training program.
18. "Substantive review" means the Board's process for determining whether an applicant for licensure, certification, or approval meets the requirements of A.R.S. Title 32, Chapter 14 and this Chapter.

~~"Supervise" means to be physically present and within sight or sound of a medical assistant, medical student, or an unlicensed resident physician in training, who is providing naturopathic medical care to a patient.~~

~~"Supervision" means a supervisor assumes legal responsibility and has oversight of activities relating to the diagnosis and treatment of a patient and the acquiring, preparing, and dispensing of devices and natural substances to a patient by a medical assistant, nurse, medical student, or a preceptee.~~

~~"Supervisor" means an individual licensed under A.R.S. Title 32, Chapter 13, 14. 17, or 29 who supervises a medical student or a preceptee, or a person licensed under A.R.S. Title 32, Chapter 14 who supervises a medical assistant or a nurse.~~

ARTICLE 8. EXPERIMENTAL MEDICINE

R4-18-801. Experimental Medicine

A procedure, medication, or device is experimental if:

1. An Institutional Review Board exits for a particular procedure, medication, or device; ~~or~~
2. The procedure, medication, or device is not generally considered to be within the accepted practice standards for the naturopathic profession~~.~~; and
3. The procedure, medication, or device is not part of the curriculum at an approved school of naturopathic medicine or approved postdoctoral training.

R4-18-802. Informed Consent and Duty to Follow Protocols

A. A physician, medical student engaged in an approved clinical training program, preceptee, or intern who conducts research involving an experimental procedure, medication, or device, shall ensure that all research subjects give informed consent to participate, which states:

1. Whether a physician, preceptee, or an intern is treating the patient;
2. That the patient or legal guardian of the patient understands:
    a. The type of treatment the patient is to receive;
    b. Each procedure that will be provided to the patient;
    c. The risks and benefits of each procedure, medication, or device to be provided;
    d. That the patient can withdraw at any time; and
    e. That the patient is voluntarily participating; and
3. The physician, medical student engaged in the approved clinical training program, preceptee, or intern has established a protocol as required by subsection (B) that meets the requirements of the institutional review board that approved the protocol.

B. A physician, medical student engaged in an approved clinical training program, preceptee, or intern, ~~that~~ who conducts research on humans involving an experimental procedure, medication, or device shall have a protocol for that research approved by an ~~Institutional Review Board~~ institutional review board.

ARTICLE 9. CERTIFICATE TO DISPENSE

R4-18-901. Definitions

The following definitions apply in this Article:

1. "Applicant" means:
    a. An individual applying for a license and a certificate; or
    b. A licensee requesting a certificate only.
2. "Auscultation" means the act of listening to sounds within the human body either directly or through the use of a

stethoscope or other means.

3. "Certificate to dispense" means an approval granted by the Board to dispense a natural substance, drug, or devise.
4. "Dispense" means the same as in A.R.S. § 32-1581(H).
5. "Drug" means the same as in A.R.S. § 32-1501(15).
6. "Hour" means 50 minutes or more of participation.
7. "Medical record" means the same as in A.R.S. § 12-2291.
8. "Nutrient" means the same as in A.R.S. § 32-1501(15)(a)(iii).
9. "Physical examination" means an evaluation of the health of an individual's body using inspection, palpation, percussion, and auscultation to determine cause of illness or disease.

R4-18-902. Qualifications for a Certificate to Dispense

A. To qualify for a certificate to dispense, an applicant shall have completed before the submission date of the application, Board approved training in the safe administration of natural substances, drugs, or devices.

B. The Board approves documentation of the following as evidence of completion of Board approved training in the safe administration of natural substances, drugs, or devices:
1. Graduation from an approved school of naturopathic medicine after January 1, 2005, as referenced in A.R.S. § 32-1525(B)(4); or
2. Completion of a 60 hour or more pharmacological course on natural substances, drugs, or devices that is offered, approved, or recognized by one of the organizations in R4-18-205(B)(1) or R4-18-205(B)(2).

C. If an applicant intends to administer a natural substance or drug intravenously, the Board approved training completed by the applicant shall include administration of a natural substance or drug by intravenous means.

R4-18-903. Application for a Certificate to Dispense; Renewal

A. An applicant for a certificate to dispense shall submit:
1. An application to the Board that contains:
   a. The applicant's:
      i. Full name,
      ii. Naturopathic license number, if known, and
      iii. Social Security number;
   b. If a corporation, a statement of whether the corporation holds tax exempt status;
   c. A statement of whether the applicant holds a drug enforcement number issued by the United States Drug Enforcement Administration, and if so, the drug enforcement number;
   d. A statement of whether the applicant has ever had the authority to prescribe, dispense, or administer a natural substance, drug, or device limited, restricted, modified, denied, surrendered or revoked by a federal or state agency or court of law, and if so, an explanation that includes:
      i. The name and address of the federal or state agency or court having jurisdiction over the matter, and
      ii. The disposition of the matter;
   e. A statement, signed by the applicant, that the applicant agrees to conform to all federal and statutes, regulations, and rules; and
   f. The date of the application; and
2. Unless exempted by A.R.S. § 32-1530, the fee required by the Board.

B. An applicant for a naturopathic license may request a certificate to dispense as part of a license application. When this request is made, approval of the naturopathic license by the Board includes approval of the certificate to dispense.

C. A certificate holder shall renew a certificate to dispense on or before July 1 of each year by submitting:
1. An application to the Board that contains:
   a. The applicant's full name;
   b. If a corporation, a statement of whether the corporation holds tax exempt status;
   c. A statement of whether the applicant has had the authority to prescribe, dispense, or administer a natural substance, drug, device limited, restricted, modified, denied, surrendered or revoked by a federal or state agency or court of law, during the one year period immediately preceding the renewal date and if so, an explanation that includes:
      i. The name and address of the federal or state agency or court having jurisdiction over the matter; and
      ii. The disposition of the matter; and
   d. A statement, signed and dated by the applicant, verifying the information on the application is true and correct and the applicant is the licensee named on the application; and
2. Unless exempted by A.R.S. § 32-1530, the fee required by the Board.

D. The Board shall grant or deny the certificate to dispense or renewal of certificate to dispense according to the time-frames in Table 1.

R4-18-904. Dispensing; Intravenous Nutrients

A. To prevent toxicity due to the excessive intake of a natural substance, drug, or device, before dispensing the natural substance, drug, or device to an individual, a certified physician shall:
1. Conduct a physical examination of the individual,
2. Conduct laboratory tests as necessary that determine the potential for toxicity of the individual, and
3. Document the results of the physical examination and laboratory tests in the individual's medical record.

B. For the purposes of A.R.S. § 32-1504(A)(8), a substance is not considered a nutrient suitable for intravenous administration if it is:
1. Not manufactured and supplied for intravenous use by a manufacturer registered with the United States Food and Drug Administration or compounded by a pharmacy licensed in Arizona, another state, or United States territory; or
2. One of the following:
   a. Silver protein, or any substance that contains silver;
   b. Cesium chloride;
   c. Hydrazine sulfate; or
   d. Lipid replacement as used in total parenteral nutrition.